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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/644,052	08/19/2003	Arthur M. Krieg	C1037.70048US00	4791

23628 7590 06/30/2006

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EXAMINER	
ARCHIE, NINA	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,052	KRIEG ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12-17,22-28,32,36,39,44,46,48,49,66,67,70,88 and 94-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-5,12-17,22-28,32,36,39,44,46,48,49,66,67,70,88 and 94-99.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 12-17, 22, 24-28, 32, 36, 39, 44, 46, 48-49, 66-67, and 95-99, drawn to immunostimulatory nucleic acid molecules having at least one internal pyrimidine-purine dinucleotide and a chimeric backbone, classified in class 536, subclass 22.1.

II. Claim 23, drawn to an immunostimulatory nucleic acid molecules having at least one internal pyrimidine-purine dinucleotide and a chimeric backbone, further comprising an adjuvant or cytokine, or an antigen, classified in class 536, subclass 22.1.

III. Claim 70, drawn to a method of modulating an immune response using to immunostimulatory nucleic acid molecules having at least one internal pyrimidine-purine dinucleotide and a chimeric backbone, classified in class 424, subclass 278.1.

IV. Claim 88, drawn to a method for treating airway remodeling comprising administering an oligonucleotide comprising a CG dinucleotide, classified in class 424, subclass 278.1.

V. Claim 94, drawn to a method for stimulating an immune response comprising administering an oligonucleotide of at least 5 nucleotides in length, classified in class 424, subclass 278.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as products. The claims of Invention I are drawn to immunostimulatory nucleic acid molecules having at least one internal pyrimidine-purine dinucleotide and a chimeric backbone, while the claims of Invention II are drawn to immunostimulatory nucleic acid molecules having at least one internal pyrimidine-purine dinucleotide and a chimeric backbone, further comprising an adjuvant or cytokine, or an antigen. The inventions are patentably distinct products because they are made by different methods and because they are physically and functionally distinct chemical entities with no common core structure.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acids of Invention I can be used in a method for treating airway remodeling.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acids of Invention I can be used in a method of modulating an immune response.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acids of Invention I can be used in a method for treating airway remodeling.

The products of Invention II are separate and distinct from the methods of Inventions III, IV, and V, wherein the products of Invention II may neither be made by nor used in the methods of Inventions III, IV, and V. In the instant case, Invention II is drawn to an oligonucleotide comprising an adjuvant, cytokine, or antigen, while the methods of Inventions III-V require the use of immunostimulatory nucleic acid molecules having at least one internal pyrimidine-purine dinucleotide and a chimeric backbone.

Inventions III-V are related as methods. The methods are distinct from one another because they have different goals as evidenced by the preamble (modulating an immune response and treating airway modeling), different method steps (administering immunostimulatory nucleic acid molecules having at least one internal pyrimidine-purine dinucleotide and a chimeric backbone; administering an oligonucleotide comprising a CG

dinucleotide; administering an oligonucleotide of at least 5 nucleotides in length), and have different final outcomes. Consequently, each method is distinct from the other.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: If applicant elects Group I, applicant must elect a single SEQ ID NO. For the elected SEQ ID NO, applicant must define the sequence and the internucleotide linkages. If applicant elects Groups II or III, applicant must define the internucleotide linkages of the nucleic acid molecule.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 12-17, 22-27, 49, 67, 70, and 95-96 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle
AU 1645

ROBERT ZEMAN
PATENT EXAMINER